

REMARKS

Upon entry of the amendments herein, claims 1-6, 8-10, 12-26 and 28-33 remain pending in the application. Claims 1, 15, 25 and 33 have been amended herein; and claim 27 has been canceled.

Claim 27 has been rejected as indefinite in light of a limitation recited in claim 25. The cancellation of claim 27 renders moot the rejection.

The Examiner states that Applicants' previous arguments "have been fully considered but they are not persuasive." Applicants note that, nonetheless, all of the previous prior art rejections have been withdrawn in favor of new ones.

Claims 1-6, 14-19, 24-27, 32 and 33 stand newly rejected under 35 U.S.C §103(a) as being obvious over U.S. Patent No. 6,042,597 to Kveen et al. in view of U.S. Patent No. 5,913,897 to Corso, Jr. et al. Applicants disagree with this assessment.

The Examiner asserts that Kveen "discloses a double-helix stent pattern," the second helix being "formed of connection elements (14) that connect peaks to valleys of adjacent turns of the first helix. The direction of the second helices is clearly defined by lines (16) in Figure 1...." However, this is not an appropriate description of what the Kveen figure shows. As disclosed in column 3, lines 12-14 of Kveen, the lines labeled 16 in Figure 1 are meant merely to show that the undulations of the single helix are out of phase. Similarly, the lines labeled

20 in Figure 6 are meant merely to show a stent in which the undulations are in phase.

There is no defined, unambiguous helical pattern going in a clear, single direction that can be traced by following line 16 or 20 of the Kveen figures. In the Kveen stents, each and every peak-valley pair along the path traced by line 16 or 20 is connected at the peak and the valley by a curvilinear connection element (14) and, thus, at each point where one of those connection elements meets a peak or valley of the undulating single helical element, one can trace a path in either of the two directions determined by the sides of the undulation in question. This is nothing like the definite, second true helical element of the instantly claimed stents, in which not every peak-valley pair is connected and a helical path is truly and clearly defined.

Throughout the Kveen disclosure, reference is made to the helical element. Even in Kveen claim 16, which recites, in addition to the single "helical band element," a "helical pattern" formed by the curvilinear elements, said pattern is merely that and not an actual continuous helical element. Furthermore, and in any event, the helical pattern formed by the curvilinear elements is running in parallel to the actual single helical element of the Kveen stent. Thus, Kveen cannot validly be said to disclose a "double-helix stent pattern" in the first

place, let alone one in which the patterns run in opposite directions.

The instant claims have been amended to recite that, as clearly shown in the instant figures, not all of the undulations of the second helix are connected by the connection elements. These amendments have been made strictly in the interest of more particularly reciting the subject matter regarded as the invention and expediting prosecution of the application to allowance. They are not in any way an acknowledgment of the validity of the Examiner's assessment of what Kveen teaches and how it relates to the instantly claimed stents. In any event, even if the portion of the Kveen stent defined by lines 16 of Kveen Fig. 1 were taken, for the sake of argument, to be a true second helical element, it can clearly be seen that all of the Kveen undulations in question are connected by the curvilinear connection elements 14. Thus, Kveen is deficient not only in that it teaches that all of the undulations on adjacent turns of the first helix must be connected but also in teaching that all of the undulations along the path of lines 16 are connected by connection elements.

The Examiner acknowledges that all of the Kveen undulations are connected by connection elements and that this is not a feature of the instantly claimed stents. The Examiner believes, however, that Corso makes up for this deficiency. Citing column

6, lines 30-51, the Examiner asserts that "Corso connects fewer than all of the undulations and teaches that only 2 to 4 second helices are necessary..." Applicants understand neither how this Corso passage can be said to provide this teaching nor what is even meant by the Examiner in referring to the idea that "only 2 to 4 second helices are necessary."

The Corso passage cited by the Examiner teaches that there can be a single helical spine or multiple helical spines and that these may have an orientation other than that which is illustrated in the figures. In any event, crucially and as can be seen in any of the pertinent Corso figures, the Corso second helical element, defined by connection of undulations in adjacent turns of the first helix and which runs in the opposite direction from the first, undulating helical element, is further defined by connection of every single possible peak-valley pair along the path of the second helix. Clearly, this is not the case in the instantly claimed stents, wherein it never happens that consecutive pairs of proximal peak-valley elements in the second helix are connected, let alone that, as in the case of the Corso stent, the peak-valley pairs in the second helix are connected consecutively throughout. Again, the present claims have been amended to set forth this feature of the invention.

Furthermore, the peaks and valleys of Corso are not connected by the discrete, elongate-link connecting elements, or

anything similar, of the instantly claimed stents. As disclosed in column 5, lines 5-15, the "connecting portions" of Corso are in fact merely the curved portions of the undulations themselves and are joined to each other via actual removal of material achieved by chemical etching or laser cutting.

Clearly, then, the Examiner has not established a *prima facie* case of obviousness. In the first place, Kveen does not even teach a double-helix stent. Secondly, the presence in the instant claims of the language "the connection elements connect fewer than all of the undulations in adjacent turns of the helix...", and the assessment of whether or not Corso teaches that not all of the undulations have to be connected, are not determinant of patentability. The fact is that all of the undulations along the path of the second helical element in Corso are connected, whereas this is not the case in the instant stents.

In fact, if the Corso peak-valley pairs were not all connected there would be no second helical element running continuously the length of the stent, as found in the instant stents. In the instant stents, as seen in the figures, there is no embodiment in which all of the peak-valley pairs of undulations in the second helix are connected by connecting elements. However, as clearly depicted in the instant figures, this is not necessary to provide a continuous second helical

element. It is respectfully requested that this rejection be withdrawn.

Claims 8-10, 12, 20-22 and 20-30 stand newly rejected under 35 U.S.C §103(a) as being obvious over the same Kveen patent in view of the same Corso patent and further in view of U.S. Patent No. 5,925,061 to Ogi et al., the latter document being the sole or primary reference cited in all of the rejections, now withdrawn, in the previous Office Action. Again, Applicants disagree with this assessment.

As clearly shown above, the combination of Kveen and Corso is ineffective in teaching or suggesting the instantly claimed stents. Whether or not Ogi teaches the transition-zone features recited in instant claim 8 and whether or not the Ogi figures depict a true second helix, as the Examiner alleges, Ogi does not provide certain fundamental features of the present stents that are lacking in the Kveen and Corso disclosures and that are necessary to establish a *prima facie* case of obviousness. Accordingly, this rejection should also be withdrawn.

Finally, claims 13, 23 and 31 stand newly rejected under 35 U.S.C §103(a) as being obvious over the same combination of Kveen, Corso and Ogi references, further in view of U.S. Patent No. 6,315,794 to Richter, the latter document having been cited as a secondary reference in one of the now-withdrawn rejections in the previous Office Action. Once again, Applicants disagree

with this assessment.

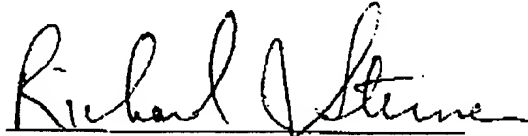
Again, the Kveen, Corso and Ogi references combined do not provide fundamental teachings required to describe or suggest the instantly claimed stents. Thus, whether or not Richter teaches the radiopacity of stent elements, Richter does not make up for the fundamental deficiencies in the teachings of the other three references. Again, this rejection should be withdrawn.

In view of the amendments and arguments herein, there are no outstanding indefiniteness issues and the claimed subject matter is free of the prior art of record. Reconsideration and allowance of the application with pending claims 1-6, 8-10, 12-26 and 28-33 are respectfully requested. Should any other matters require attention prior to allowance, it is requested that the Examiner contact the undersigned.

No other fees should be due in connection with this communication. However, should it be determined that an additional fee is required for any reason, the Commissioner is hereby authorized to charge it to Deposit Account No. 23-1703.

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Respectfully submitted,



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Enclosures: Form PTO/SB/30 (2 copies) and Form PTO/SB/21